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| APPLICATION NO. FILING DATE |                  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.       |      |  |
|-----------------------------|------------------|----------------------|---------------------|------------------------|------|--|
| 10/532,662                  |                  | 01/19/2006           | Satoshi Omura       | 8012-1317              | 5881 |  |
| 466                         | 7590             | 12/05/2006           |                     | EXAMINER               |      |  |
| YOUNG                       | & THOM           | PSON                 | YOUNG, HUGH PARKER  |                        |      |  |
| 745 SOUT<br>2ND FLO         | TH 23RD ST<br>OR | FREET                | ART UNIT            | PAPER NUMBER           |      |  |
| ARLINGT                     | ON, VA           | 22202                | 1654                |                        |      |  |
|                             |                  | •                    |                     | DATE MAILED: 12/05/200 | 6 ·  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   | 7             | Application No. Ap                    |                                       | Applicant(s)       | pplicant(s) |  |  |  |  |  |
|--|---|---------------|---------------------------------------|---------------------------------------|--------------------|-------------|--|--|--|--|--|
| Office Action Summary  |   |               | 10/532,662                            |                                       | OMURA ET AL.       |             |  |  |  |  |  |
|  |   |               | Examiner                              |                                       | Art Unit           |             |  |  |  |  |  |
|  |   |               | Hugh P. You                           |                                       | 1654               |             |  |  |  |  |  |
|  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply |               |                                       |                                       |                    |             |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| Status   |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| 1) 又   | Responsive to communication(s) file   | ed on 23 Octo | ober 2006.                            |                                       |                    |             |  |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  | Fhis action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |               |                                       |                                       |                    |             |  |  |  |  |  |
| '=   | Since this application is in condition  | •             |                                       |                                       | secution as to the | e merits is |  |  |  |  |  |
| ,  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.                     |               |                                       |                                       |                    |             |  |  |  |  |  |
| Disposition of Claims  |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| 4)⊠  | Claim(s) 1-15 is/are pending in the a   | application.  |                                       |                                       |                    |             |  |  |  |  |  |
|  | 4a) Of the above claim(s) <u>2-6,11 and 12</u> is/are withdrawn from consideration.                                   |               |                                       |                                       |                    |             |  |  |  |  |  |
|  | Claim(s) is/are allowed.  |               |                                       |                                       |                    |             |  |  |  |  |  |
| -  | )⊠ Claim(s) <u>1,7-10 and 13-15</u> is/are rejected.  |               |                                       |                                       |                    |             |  |  |  |  |  |
|  | ☐ Claim(s) is/are objected to.  |               |                                       |                                       |                    |             |  |  |  |  |  |
| <u> </u>   | Claim(s) are subject to restrict  | tion and/or e | election req                          | uirement.                             |                    |             |  |  |  |  |  |
|  | on Papers   |               | · · · · · · · · · · · · · · · · · · · |                                       |                    |             |  |  |  |  |  |
|  | •   |               |                                       |                                       |                    |             |  |  |  |  |  |
|  | The specification is objected to by th  |               |                                       |                                       |                    |             |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| Priority u   | nder 35 U.S.C. § 119  |               |                                       |                                       |                    |             |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |               |                                       |                                       |                    |             |  |  |  |  |  |
| Attachment(s)  |   |               |                                       |                                       |                    |             |  |  |  |  |  |
|  | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (F                                       | PTO-948\      | 4                                     | Interview Summary Paper No(s)/Mail Da |                    |             |  |  |  |  |  |
| 3) 🛛 Infom   | nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date  | 10-940)       | 5<br>6                                | Notice of Informal Pa                 |                    |             |  |  |  |  |  |

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### **DETAILED ACTION**

This is the first Office Action on the merits of application 10/532,662. There are fifteen claims pending, claims 1, 7-10, and 13-15 of which are presently under consideration.

#### Restriction made final

1. Applicant's election with traverse of Group I, claims 1, 7-10 and 13-15 in the reply filed on October 23, 2006 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I-IV have a unique technical feature which is not shown by the other groups. This is not found persuasive because the unique technical feature shared by the groups, the depsipeptide of the formula of claim 1 is not a contribution over the art because it is anticipated by Kalbe et al. (2001, WO 01/62268 A1; and 2002, WO 02/00202A1), in the depsipeptide disclosed in formula Ia, page 13 and formula Ia, page 14, respectively, thus showing the peptides claimed as not being a contribution over the art.

The requirement is still deemed proper and is therefore made FINAL.

# Objections to the Specification

2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The sentence beginning on line 11, page 1, is grammatically incorrect in either number or lack of an accessory verb. This first sentence on page 2 misuses the word "induces." The last sentence of page 2 is non-

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idiomatic. The use of the word "genus" when referring to fungi in line 10, page 4, is taxonomically incorrect. The disclosure is replete with similar informalities.

Appropriate correction is required.

## Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 1, 7-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalbe et al, 2001, WO 01/62268 A1 (PCT/EP01/01392). Kalbe et al. teach a depsipeptide anti-endoparasite agent as shown in Formula Ia, page 13, lines 15 et sequitur. The 24-member ring core structure and substituents recited in the listings of R-groups anticipate the depsipeptide of formula FKI-1033 as claimed in the instant application. Specifically, Kalbe et al's Formula Ia recites a C1 alkyl (methyl) group at position R1a, a C1 alkyl (methyl) group at position R2a, a C5 alkyl (pentyl) group at position R3a, a C1 alkyl (methyl) group at position R4a, a C5 alkyl (pentyl) group at position R5a, a C1 alkyl (methyl) group at position R6a, a C5 alkyl (pentyl) group at position R7a (mislabeled as R75a in the diagram on page 13), a C1 alkyl (methyl) group at position R8a, a C5 alkyl (pentyl) group at

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position R10a, a C1 alkyl (methyl) group at position R11a, and a C1 alkyl (methyl) group at position R12a. Kalbe et al's depsipeptide of Formula Ia is claimed in the instant claims 1, 9, 10, 13, 14 and 15. The other limitations recited in the instant claims are to characteristics inherent in the molecule, directly derived from and attributable to its structure. The characteristics are: Ryanodine-binding ability (instant dependent claim 7 and independent claims 9, 13 and 14) and the insecticidal and antihelminthic functions (instant dependent claim 8 independent claims 10, 13 and 15).

5. Claims 1, 7-10 and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Kalbe et al, 2002, WO 02/00202 A1 (PCT/EP01/06836). Kalbe et al. teach a depsipeptide anti-endoparasite agent as shown in Formula Ia, page 14, lines 1 et seguitur. The 24-member ring core structure and substituents recited in the listings of R-groups anticipate the depsipeptide of formula FKI-1033 as claimed in the instant application. Specifically, Kalbe et al's Formula la recites a C1 alkyl (methyl) group at position R1a, a C1 alkyl (methyl) group at position R2a, a C5 alkyl (pentyl) group at position R3a, a C1 alkyl (methyl) group at position R4a, a C5 alkyl (pentyl) group at position R5a, a C1 alkyl (methyl) group at position R6a, a C5 alkyl (pentyl) group at position R7a, a C1 alkyl (methyl) group at position R8a, a C5 alkyl (pentyl) group at position R9a, a C1 alkyl (methyl) group at position R10a, a C1 alkyl (methyl) group at position R11a, and a C1 alkyl (methyl) group at position R12a. Kalbe et al's depsipeptide of Formula la is claimed in the instant claims 1, 9, 10, 13, 14 and 15. The other limitations recited in the instant claims are to characteristics inherent in the molecule, directly derived from and attributable to its structure. These inherent

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characteristics are: Ryanodine-binding ability (instant dependent claim 7 and independent claims 9, 13 and 14) and the insecticidal and antihelminthic functions

(instant dependent claim 8 independent claims 10, 13 and 15).

## Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D.

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JON WEBER SUPERVISORY PATENT EXAMINER

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